REMARKS

Claim 1 has been amended to clarify the invention. Support for the amendments to Claim 1 can be found in Claims 3 and 4 which have been canceled without prejudice. Claims 5 and 6 have been amended to change their dependencies. Accordingly, Claims 1, 2 and 5-10 are pending in this application. The amendments do not constitute the addition of new matter to the specification. Applicant respectfully requests entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Rejection of Claims 1-4 and 7-10 Under 35 U.S.C. § 112

Claims 1-4 and 7-10 have been rejected under 35 U.S.C. § 112, first paragraph, because the Examiner states that the specification does not reasonably provide enablement for evaluating sensitivity to any other drug in other animals or humans for any other gene. Claim 1 has been amended for clarification. Applicant respectfully traverses this rejection.

(1) As to drugs other than morphine and (-)-U-50488, the drug in Claim 1 has been amended to "a drug of which target is μ-opioid receptor" (see page 8, lines 7-10 of the present specification). As shown in the Examples of the present specification, the claimed method is applicable to not only morphine but also (-)-U-50488, both of which are categorized in opioid. One of ordinary skill in the art should be readily able to apply the claimed method to not only morphine and (-)-U-50488 but also other opioid.

(2) As to humans or animals other than mice, the target subject in Claim 1 has been amended to "a human or a mouse". The claimed method is applicable to not only a mouse but also a human because as with a mouse, a human has polymorphisms in an untranslated region of mRNA of μ-opioid receptor gene. The declaration attached herewith shows that Japanese subjects have 56 polymorphisms in an untranslated region of mRNA of μ-opioid receptor gene. This fact clearly indicates that the untranslated region of mRNA of μ-opioid receptor gene is diverse among individuals not only in mice but also in humans. Thus, one of ordinary skill in the art could reasonably and readily expect that similarly to the case of mice, the untranslated region in humans significantly affects the stability of mRNA to cause individual differences in the amount of mRNA, and the size of mRNA corresponds to the amount of the μ-opioid receptor protein to cause individual differences in the protein amount and eventually cause individual differences in the effect of an opioid (see page 8, lines 11-23 of the present specification).

(3) As to genes other than μ-opioid receptor gene, the gene in Claim 1 has been amended to "a μ-opioid receptor gene." Thus, the method of the amended claims can readily be performed by one of ordinary skill in the art.

In conclusion, it is respectfully requested that the rejection under 35 U.S.C. § 112 be withdrawn.

Rejection of Claims 1, 2 and 7-10 Under 35 U.S.C. § 102

Claims 1, 2 and 7-10 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Baumann et al. (Mol. Cell. Biol., vol. 6, pp. 2551-2561 (1986)). As mentioned above, Claim 1 has been amended for clarification. Claim 1 is independent and the remaining claims are dependent ultimately on Claim 1. Applicant respectfully traverses the rejection.

A drug of the invention recited in Claim 1 as amended herein has been limited to opioid. On the other hand, dexamethasone, a drug in Baumann et al., is not included in opioid. Therefore, the method of the claimed invention is apparently different from that of Baumann et al. Thus, Claim 1 and the claims dependent ultimately on Claim 1 could not be anticipated by Baumann et al.

Further, Baumann et al. discloses that untranslated region of mRNA of the rat α_1-acid glycoprotein affects the positive regulation of α_1-acid glycoprotein by dexamethasone. However, opioid such as morphine is apparently different in the structure and the target receptor from dexamethasone. Therefore, one skilled in the art could not predict whether or not an untranslated region of mRNA of μ-opioid receptor gene could affect the sensitivity to opioid. Consequently, the claimed invention is patentable. It is respectfully requested that the rejection under 35 U.S.C. § 102 be withdrawn.

Rejection of Claims 1-10 Under 35 U.S.C. § 102

Claims 1-10 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Ikeda et al. (J. Neurosci., vol. 21, pp. 1334-1339, February 2001).

The authors of the publication are the same as in the present application except Tomino Ichikawa who is a person added in the publication. The present inventors have declared that the invention disclosed in the publication was made by the parties identical to the present inventors,

and Tomino Ichkawa was not an inventor of the published invention as shown in the attached 37 C.F.R. § 1.132 declaration signed by the present inventors. Accordingly, Ikeda et al. could not serve as prior art under 35 U.S.C. § 102(a). Thus, it is respectfully requested that the rejection be withdrawn.

CONCLUSION

In light of the Applicant's amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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